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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,978	01/21/2004	Howard Cohen	479-P-007B	4044

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,978

Applicant(s)

COHEN ET AL.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 16, 21-23, 25-37 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-15, 17-20, 24, 38, 39, and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 6/15/06 have been fully considered. Applicant's amendments overcame the rejection under 35 U.S.C. 102(e) as being anticipated by Gauchet et al (6,733,532).

Regarding the rejection in view of Cauthen (6,019,792) in view of Zdeblick et al (6,881,228), the Examiner believes that Cauthen could be argued having substantially flat plate members; note the inner surfaces are generally flat, however, a combination rejection using Zdeblick et al clearly teaching both exterior configurations, curved and generally flat is believed to be a stronger rejection. The combination rejections are believed to be very obvious to one having ordinary skill in the art. Applicant's invention of having a means for temporarily stabilizing the flexible supporting means is taught by Cauthen.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 11-15, 17-20, 24, 38, 39, and 43-46 (all claims not withdrawn) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new limitation added to claims 1 and 24 is new matter, "*wherein said at least one temporary stabilizing means allows limited axial rotation of said upper and lower substantially flat plate members*". First, "at least one" is broader than what is taught in the disclosure; what would be the second. Additionally, "*allows limited axial rotation*" is not supported in the original disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 11-15, 17-20, 24, 38, 39, and 43-46 (all claims not withdrawn) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 24, how does the temporary stabilizing means allow limited rotation? In viewing applicant's figure 16, element 103 appears to allow full rotation, not limited rotation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11-13 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (6,019,792) in view of Zdeblick et al (6,881,228).

Cauthen teaches an artificial disc for placement between adjacent vertebrae comprising:

at least two plate members 20, 22, each plate member having a corresponding surface:

at least one means for temporarily stabilizing said plate members for a certain period of time to allow at least two of said plate members to osteo-integrate with adjacent vertebrae (see elements 82, 94, etc and at least 3:7 et seq. and 6:43 et seq.); and

at least one flexible supporting means (see element 90 in figure 5) interposed between said plate members and abutting inner bearing surfaces, said flexible support means flexibly supporting said plate members after said certain period of time.

However, Cauthen teaches a plate members which have a generally semi-circular cross-section and not a substantially flat plate. Zdeblick et al also teaches various artificial disc prostheses having a semi-circular cross-sections (at least figures 3 and 28) like Cauthen and, additionally, teaches a flat plate configuration as shown in figures 38-41 and 7. It would have been obvious to one having ordinary skill in the art have substituted the flat plat configuration as taught by Zdeblick et al on the disc of Cauthen as a know alternative shape in the art which does not require a cylindrical removal of the vertebrae bone would deemed appropriate by the surgeon.

Regarding claim 4, the plate members are made of titanium and therefore, ball element 42 is titanium which is interpreted as a portion of the flexible supporting means.

Regarding at least claim 12, "rigid collar surrounding", see 7:7 et seq. teaching filling a biodegradable polymer between the plate members which forms a collar.

Regarding at least claim 13, "supplemental support", see the bioabsorbable endcap 90.

Regarding claim 1, "compressibly" describing the flexible supporting means, as noted by applicant, Cauthen teaches element 90 as "resilient to absorb implant loading" which is interpreted by the Examiner as "flexibly and compressibly".

Claims 24 and 14-15, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (6,019,792) and Zdeblick et al (6,881,228) and further in view of Shinn et al (5,683,465).

Cauthen and Zdeblick et al teaches the artificial disc as described above including using drugs for bone ingrowth (see 8:12 et seq.), however, they are silent regarding a "substance with anti-microbial drug eluting factors". Shinn et al teaches a similar artificial disc which uses drugs to promote healing including an antibiotic. It would have been obvious to one having ordinary skill in the art have used an antibiotic as taught by Shinn et al or any other drug known in the art of prosthetics to promote healing, lessen the chances of infection or simply improve implantation of the disc in bone.

Regarding claims 14-15 and 38-39, Cauthen teaches the artificial disc as described above including using "one or more stabilizing means for temporarily rigidly coupling the first [plate] and second [plate]. It would have been obvious to one having ordinary skill in the art to have utilized any know stabilizing means known in the art as deemed necessary by the surgeon. Additionally, lacking any criticality in the specification, the use of the specifically claimed supplemental support.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

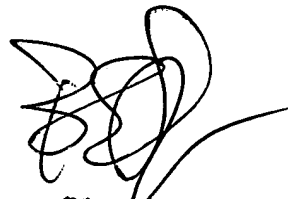
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BRUCE SNOW
PRIMARY EXAMINER